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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,307	03/21/2001	Naoto Oku	50026/024001	2668
21559	7590	09/30/2005		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER EPPS FORD, JANET L	
			ART UNIT	PAPER NUMBER
			1633	

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,307

Applicant(s)

OKU ET AL.

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 53-63, 68, 83 and 85 is/are allowed.
- 6) ☒ Claim(s) 64-67, 69-82 and 84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The rejection of claims 69-71 under 35 USC 112, 2nd paragraph is withdrawn in response to Applicant's amendment to the claims.

Response to Arguments

Claim Rejections - 35 USC § 103

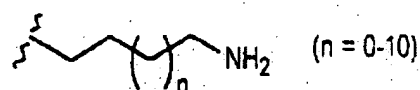
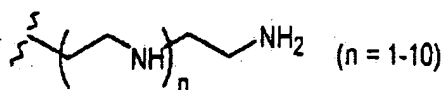
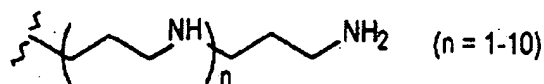
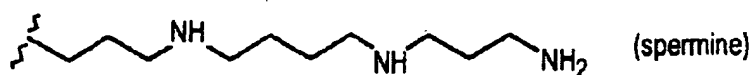
3. The rejection of claims 68, 83, and 85 under 35 USC 103(a) as being unpatentable over Kahne, is withdrawn in response to Applicant's arguments. Since the disclosure of Kahne essentially reads on the addition of cholic acid based hydrophobic moieties to spermine or tetraethylenepentamine, there is no apparent motivation to substitute the cholic acid based moieties of Kahne with the aliphatic groups recited in instant claims 68, 83 and 85, therefore the rejection under 35 USC 103(a) over Kahne with respect to these claims is withdrawn. However, the cholic acid based moieties of Kahne comprise a structure that is very similar to that of cholesterol, and cholesterol is known in the art as useful in liposomal gene delivery compositions (see Kahne, col. 3, lines 8-15), therefore the rejection over claim 67 is maintained.
4. Claims 64-67, 69-82, and 84 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kahne (US 5,780,444), for the reasons of record set forth in the prior Office Action.
5. Applicant's arguments filed 8-25-05 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the Office has

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not established a *prima facie* case of obviousness. According to Applicants, MPEP § 2144.06, cited by the examiner to support the instant rejection, is not relevant to the instant claims because this section of the MPEP describes the obvious mixture of two prior art compounds to contain two separate compounds, and does not teach the obviousness of a single compound as instantly claimed. Applicants traverse on the grounds that claim 64 and the dependent claims are not directed to a mixture of two polyamines having a single hydrophobic group, but to polyamines having two hydrophobic groups.

In regards to motivation to combine, and the examiner's reliance upon MPEP 2144.06, contrary to applicant's assertions, although there is references to "mixtures" in this portion of the MPEP, it is clear that this passage supports the obviousness of combining two separate compositions to form a third *single* composition. Kahne clearly discloses the hydrophobic modification of tetraethylenepentamine or spermine, and the use of the resultant compound for gene delivery. Kahne describes multiple polyamines that may be attached to the hydrophobic backbone of formula I, see Figures 3-4 (col. 7, lines 15-17). Figure 3 of this reference describes polyamine structures that are useful in the invention of Kahne:

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The 4th polyamine structure (particularly wherein $n=10$) set forth above encompasses wherein a tetraethylenepentamine is linked in a linear manner.

Applicant's arguments do not take the place of evidence. Absent evidence to the contrary, since Applicants have not provided any evidence of unexpected results to demonstrate that their compositions have superior properties in comparison to the compositions of Kahne, linking together two or more tetraethylenepentamine or spermine structures, and further modifying these with two or more hydrophobic groups, to use the resultant compound for DNA transfection, is not inventive since the prior art clearly teaches that tetraethylenepentamine or spermine structures comprising a hydrophobic moiety are useful for DNA transfection. The essential elements of Applicant's invention are clearly disclosed by the Kahne reference, Applicant's claims represent an obvious variation of the Kahne reference.

6. Applicants argue that the compounds of Kahne are amphipathic, having both hydrophilic and hydrophobic character, and does not read on a hydrophobic group,

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Kahne focuses on these amphipathic compounds that lack a hydrophobic group, it does not suggest a polyalkylenimine having two hydrophobic groups as recited in the instant claims (see page 12, 1st paragraph of the response filed 8-25-05).

Contrary to Applicant's assertions, although the compounds of Kahne comprise both a hydrophilic and a hydrophobic portion, it is clear that these compounds have a hydrophobic portion as evidenced by compounds set forth in Table 7, col. 4, of Kahne. Furthermore, Applicant's compounds are amphipathic as well, comprising a positively charged hydrophilic portion, the polyalkylenimine portion, and a hydrophobic portion.

7. Furthermore, Applicants argue that Kahne simply does not teach or suggest all of the limitations of the instant claims; in particular Applicants assert that Kahne doesn't teach the inclusion of two hydrophobic groups (page 11 of Applicant's response). The examiner recognizes that the Kahne reference does not anticipate each and every aspect of the instant invention, however the disclosure of Kahne is considered to render obvious the instant claims, for the reasons of record. Kahne clearly directs the skilled artisan to use compositions of tetraethylenepentamine or spermine compounds, comprising a hydrophobic portion, to mediate the cellular uptake of DNA (see col. 6). Applicant's invention, that comprises a polyalkylenimine or salt comprising two or more tetraethylenepentamine or spermine and two or more hydrophobic groups, is considered an obvious variation of Kahne.

Conclusion

8. Claims 53-85 are presently pending. 53-63, 68, 83, and 85 are free of the prior art. 64-67, 69-82, and 84 remain rejected for the reasons of record.

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9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 9:30 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 517-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


Janet L. Epps-Ford
Examiner
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JLE